

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 49 and 51 have been amended, claim 50 has been cancelled, and new claims 57-70 have been introduced. Claims 49 and 51-70 remain pending. No excess claim fees are due.

The rejection of claims 49-56 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,479,545 to Levinson et al. (“Levinson”) in view of <http://www.vitaminworld.com/pages/file> (“Vitamin world reference”) is respectfully traversed.

Levinson teaches compositions that provide improved nutritional support for premenopausal and menopausal women and/or relief from symptoms associated with menopause, as well as prophylactic effects, and methods for their use. The composition includes one or more essential fatty acid components in an amount of ~10 mg to ~1,000 mg, a calcium compound or derivative in an amount of ~400 mg to about 2500 mg, and a folic acid compound or derivative in an amount of ~0.4 mg to ~5 mg, where the weight ratio of the essential fatty acid to the calcium compound is about 1:0.4 to about 1:250 per dose. Levinson considers these components and their ratios *critical* (see column 3, lines 37-41). In addition, Levinson suggests the composition may also include, among a long list of other additives, the amino acid methionine.

While the PTO cites the Vitamin World reference as evidence that single-unit dosages containing effective amounts of methionine were available, Levinson in no way suggests using single-dosage units of methionine. Quite the contrary, Levinson makes clear that the methionine is *not* in a single dosage unit, and that methionine—as a noncritical component—does not need to be present and, even if present, is *not* responsible for the therapeutic effects of the Levinson composition. Indeed, methionine, if present, is merely an additive. Thus, Levinson fails to suggest that any of the recited amino acids, let alone methionine, can be used as an active agent to treat hot flashes.

Moreover, Levinson fails to provide any guidance regarding how much methionine is needed (i.e., an effective amount) to control symptoms of menopause. Because Levinson in no way suggests that methionine (or any other listed amino acid) can be used in any amount to treat hot flashes, persons of skill in the art would have had no reason even to consider using the single-dosage unit of methionine that is described by the Vitamin World reference.

Finally, it should be pointed out that Levinson lists all 20 essential amino acids as additives. To the extent that any of these are preferred for one reason or another, it is not methionine, but rather leucine, isoleucine, and valine (*see* column 14, line 65 to column 15, line 5). Thus, if Levinson makes any suggestion about the amino acids being effective for treating symptoms of menopause (which applicant believes it does not), then that suggestion only applies to the three preferred amino acids and not the other 17 essential amino acids, including methionine.

For all these reasons, the rejection of claims 49-56 for obviousness over Levinson in view of Vitamin World is improper and should be withdrawn.

Because claims 57-63 do not recite methionine, these claims should be allowable over the art of record. Because Levinson fails to teach or suggest administering “an effective amount” of methionine to treat hot flashes for the reasons noted above, claims 64-70 are also allowable over the art of record.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: January 30, 2008

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1128
Facsimile: (585) 263-1600